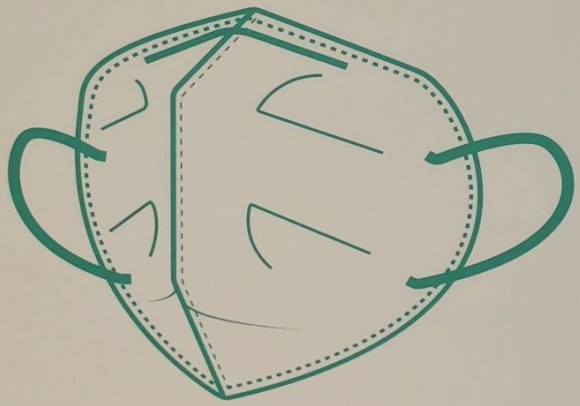
DADDY'S CHOICE Purism

DADDY'S CHOICE Purism

CE 0598

Model: Purism
Regulation(EU) 2016/425
EN 149:2001+A1:2009 FFP2 NR



Atemschutzmaske

20 PCS

CE 0598
Model: Purism
Regulation(EU) 2016/425
EN 149:2001+A1:2009 FFP2 NR
20 PCS
DADDY'S CHOICE
Purism FFP2 NR
EN149:2001+A1:2009
CE 0598

Certificate FI20/966301

Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Tiandingfeng road Garden street,
Economic Development Zone,
Linyi County, Dezhou City,
Shandong Province

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425

Module B, EU type-examination

This certificate is valid from 05 August 2020 until 05 August 2025
1. Certified since 05 August 2020

Authorised by

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380, Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

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Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

Daddy's Choice (logo) Purism white folded half mask, consisting of a white five layer (polypropylene/ polypropylene/ polypropylene /Polyethylene&Polyethylene terephthalate/ polypropylene) disposable particle filtering half mask, with polypropylene/iron wire nose clip, nylon/ polyurethane ear band, foam and polypropylene retaining clip.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

Certification is based on technical file reference:

Protective face mask/ Purism, version 1, dated: 2020-07-01.

SGS Reference Number UK/CRS 241399.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request.

EU-KONFORMITÄTSERKLÄRUNG

Hersteller

Name: Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Adresse: Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou City Shandong Province

erklärt, dass die nachfolgend beschriebene neue PSA

Beschreibung der Produkte	Atemschutzmaske
Produktstil / Bestell-Nr	Purism
Produktfarbe und -typ	Weiß Nicht wiederverwendbarer, gefalteter Typ
Einstufung	FFP2 NR

entsprechen der Verordnung (EU) 2016/425 und der harmonisierten Norm

EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

die EU-Musterprüfung (Modul B) durchgeführt und das EU-Musterprüfzeugnis FI 20/966301 ausgestellt.

Die PSA unterliegt dem Konformitätsbewertungsverfahren: EU-Typprüfung (Modul B) gemäß Anhang V und entweder Konformität mit dem Typ auf der Grundlage der internen Produktionskontrolle plus überwachten Produktprüfungen in zufälligen Intervallen (Modul C2) oder Konformität mit dem Typ zur Qualitätssicherung des Produktionsprozesses (Modul D) unter Überwachung der benannten Stelle SGS Fimko Oy, benannte Stelle Nr. 0598..

Unterzeichnet im Namen des Unternehmens

Name: Zhang Wenkun

Position: Vertreter des Managements

Unterschrift: Zhang Wenkun

Datum: 2020.08.07

Certification and test documentation

Type:	FFP2 Atemschutzmaske Purism
Manufacturer:	Shandong Daddy's Choice Health Science and Technology Co.,LTD
Certified by:	SGS Fimko Oy Takomotie 8, FI-00380 Helsinki, Finland Notified Body No. 0598
Standard:	EN 149+A1:2009
Regulation:	Personal Protective Equipment (EU) 2016/425 – Category 3
Date of Certification:	13.08.2020

Attachements:

EU Type Examination Certificate

Certificate of Conformance

CE-Declaration of manufacturer

SGS

中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report **SL22002253011901TX** **Date: Jun 04,2020** **Page 1 of 10**

SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO., LTD
TIANDINGFENG ROAD GARDEN STREET ECONOMIC DEVELOPMENT ZONE LINYI COUNTY DEZHOU CITY SHANDONG PROVINCE CHINA,251500 CN

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)mask(Protective face mask)
Sample color	:	White
Composition	:	Non-woven fabric melt-blown fabric
Manufacturer	:	SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO., LTD
Supplier	:	SHANDONG DADDY'S CHOICE HEALTH SCIENCE AND TECHNOLOGY CO., LTD
Style No	:	Purism

Sample Receiving Date	:	May 04, 2020
Testing Period	:	May 04, 2020 - Jun 04, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	:	Selected test(s) as requested by applicant

Conclusion:

Sample No.	**Recommendation level**
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Angel Guo (Account Executive)

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Test Result

Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking*
(EN 149:2001+A1:2009)

Clause 7.4 Packaging*
(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Comply	Pass

Clause 7.5 Material*
(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Comply	Pass
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	

Clause 7.6 Cleaning and Disinfecting*
(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N.A.

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Clause 7.7 Practical Performance*

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass

Clause 7.8 Finish of Parts*

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage*

(EN 149:2001+A1:2009, Clause 8.5)

Test Requirement	Results	Comment
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3	Detail refer to Appendix 1	Pass

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
1#	1	A.R.	6.6	7.2	7.1	7.2	6.7	7.0
2#	2	A.R.	6.3	6.7	7.1	7.0	6.4	6.7
3#	3	A.R.	6.6	7.1	7.3	7.3	6.6	7.0
4#	4	A.R.	7.0	7.8	7.8	8.0	7.4	7.6
5#	5	A.R.	6.4	7.1	7.2	7.2	6.6	6.9
6#	6	T.C.	6.5	7.3	7.4	7.4	6.7	7.1
7#	7	T.C.	6.4	7.2	7.6	7.2	6.8	7.0
8#	8	T.C.	6.6	7.3	7.2	7.2	6.7	7.0
9#	9	T.C.	7.2	8.0	7.9	8.1	7.5	7.7
10#	10	T.C.	7.1	7.6	8.1	7.8	7.3	7.6
50 out of the 50 individual exercise results ≤ 11 %					Pass			
10 of the 10 individual arithmetic means ≤ 8%								

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Facial Dimension

Subject	Face length(mm)	Face Width(mm)	Face Depth(mm)	Mouth Width(mm)
1#	120	130	109	59
2#	122	140	115	65
3#	119	160	139	55
4#	112	122	119	63
5#	110	130	118	60
6#	115	119	110	59
7#	112	123	113	55
8#	103	130	100	50
9#	118	139	130	63
10#	120	135	125	50

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Clause 7.9.2 Penetration of Filter Material*

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 2	Pass

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.1	Pass
		12	0.2	
		13	0.1	
	Simulated wearing treatment	14	0.2	
		15	0.1	
		16	0.1	
	Mechanical strength +Temperature conditioned	17	0.3	
		18	0.2	
		19	0.2	
Paraffin oil test	As received	20	0.2	
		21	0.3	
		22	0.2	
	Simulated wearing treatment	23	0.3	
		24	0.2	
		25	0.2	
	Mechanical strength +Temperature conditioned	26	0.8	
		27	0.7	
		28	0.9	
Flow conditioning: Single filter: 95.0 L/min				

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Clause 7.10 Compatibility with Skin*
(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	No irritation or any other adverse effect to health	Pass

Clause 7.11 Flammability*
(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	Assessment
As received	29	Burn for 0.1s	Pass
	30	Burn for 0.1s	
Temperature conditioned	31	Burn for 0.1s	
	32	Burn for 0.1s	

Clause 7.12 Carbon Dioxide Content of The Inhalation Air*
(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result		Assessment
As received	33	0.7125%	Mean value :0.71%	Pass
	34	0.7135%		
	35	0.7145%		

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Clause 7.13 Head Harness*

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Comply	

Clause 7.14 Field of Vision *

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.15 Exhalation Valve(s)*

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
(a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	Not applicable due to exhalation valve	N.A
(b) If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	Not applicable due to exhalation valve	
(c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	Not applicable due to exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to exhalation valve	

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Clause 7.16 Breathing Resistance*
(EN 149:2001+A1:2009, Clause 8.9)

Test Requirement	Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.	Detail refer to Appendix 5	Pass

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Appendix 5: Summarization of Test Data
Breathing resistance (mbar)

As received	Flow rate		Specimen No.36					Specimen No.37					Specimen No.38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.2	0.3
		95 l/min	1.1	1.2	1.1	1.1	1.2	1.2	1.2	1.1	1.1	1.1	1.1	1.2	1.1	1.1	1.1
	Exhalation	160 l/min	1.5	1.6	1.6	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.5	1.6	1.6	1.6
Simulated wearing treatment	Flow rate		Specimen No.39					Specimen No.40					Specimen No.41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.3	0.2	0.3	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.2	0.2	0.2
		95 l/min	1.1	1.2	1.2	1.1	1.1	1.1	1.2	1.2	1.1	1.1	1.1	1.2	1.1	1.2	1.1
	Exhalation	160 l/min	1.6	1.6	1.5	1.6	1.6	1.6	1.6	1.7	1.6	1.7	1.7	1.7	1.6	1.7	1.7
Temperature conditioned	Flow rate		Specimen No.42					Specimen No.43					Specimen No.44				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.2	0.2	0.2	0.3	0.2	0.2	0.3
		95 l/min	1.1	1.2	1.2	1.2	1.1	1.1	1.2	1.2	1.1	1.1	1.1	1.2	1.1	1.1	1.1
	Exhalation	160 l/min	1.7	1.5	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8
Assessment	Pass																

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

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Clause 7.17 Clogging*

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment
Clause 7.17.2 Breathing resistance Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow	Optional for single shift device only	N.A
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Optional for single shift device only	N.A

Classification	Maximum penetration of test aerosol	
	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
	%	%
	max.	max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Clause 7.18 Demountable Parts*

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	Not applicable	N.A

* Test items were carried out by (Jiangsu Guojian Testing Technology Co., Ltd)（CNAS L10118）assessed as competent, were not included in the CNAS Accredited Schedule for our laboratory.

pH Value

Test Method:According to ISO 3071:2020; 0.1mol/l KCL extraction

pH value	6.28	4.0 – 7.5	PASS

Note: pH value of extraction medium 5.80
Temperature of the extraction solution 21.6℃

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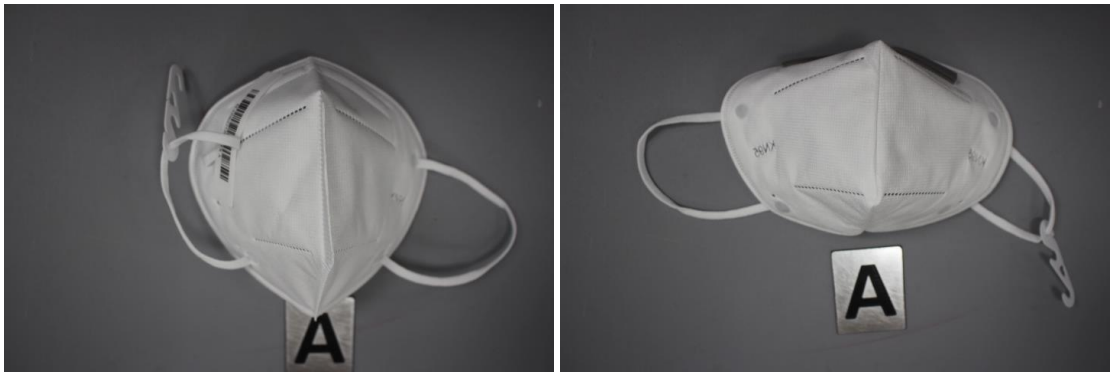
Test	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%
pH Value	3.98%

Sample photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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DADDY'S CHOICE Purism

Certificate CN20/42187

The management system of

Shandong Daddy's Choice Health Science and Technology Co., Ltd.

Tiandingfeng Road, Garden Street Economic Development Zone,
Linyi County, Dezhou City, Shandong Province, 100024, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module C2

For the following activities

Manufacture of Daddy's Choice (logo) Purism white folded Particle Filtering Half Mask.
(Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of Directive 89/686/EEC.)

This certificate is valid from 13 August 2020
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 13 August 2020

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

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DADDY'S CHOICE Purism

ERKLÄRUNG DER KONFORMITÄT DER EU

Hersteller No.DC0001

Name: Shandong Daddy's Choice Health Science and Technology Co.,Ltd.

Adresse: Tiandingfeng road Garden street Economic Development Zone Linyi County Dezhou City Shandong Provinz

erklärt, dass die im Folgenden beschriebene neue PPE

Beschreibung der Produkte	Schutzmaske für Gesicht
Produktstil/Bestellnummer	Purism
Produktfarbe und -typ	Weiß Nicht wiederverwendbar, gefaltet
Klassifizierung	FFP2 NR

entsprechen der Verordnung (EU) 2016/425 und mit harmonisierter Norm

EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

hat die EU-Baumusterprüfung (Modul B) durchgeführt und das EU-Baumusterprüfbescheinigung FI 20/966301 ausgestellt.

Die EVP unterliegt dem Konformitätsbewertungsverfahren: EU-Baumusterprüfung (Modul B) gemäß Anhang V und entweder Konformität mit dem Typ auf der Grundlage interner Produktionskontrolle und überwachte Warenkontrollen in Zufallsintervallen (Modul C2) unter

SGS Fimko Oy, NB 0598.

Unterzeichnet im Namen des Unternehmens

Name: Zhang Wenkun

Position: Geschäftsführer

Unterschrift: Zhang Wenkun

Datum: 2020.08.07